

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Chiara MALVOLTI, et al.

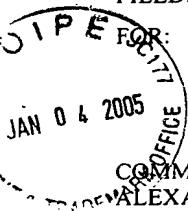
SERIAL NO: 10/030,101

GAU: 1616

FILED: May 3, 2002

EXAMINER: HAGHIGHATIAN, M.

FORMULATIONS OF STEROID SOLUTIONS FOR INHALATORY ADMINISTRATION



INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
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CERTIFICATION

- Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
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U.S. PATENT AND TRADEMARK OFFICE  
JAN 06 2005  
**LIST OF RELATED CASES**

| <u>Docket Number</u> | <u>Serial or Patent Number</u> | <u>Filing or Issue Date</u> | <u>Patent Appl. Publication No.</u> | <u>Inventor/Applicant</u> |
|----------------------|--------------------------------|-----------------------------|-------------------------------------|---------------------------|
| *217941US0 PCT       | 10/030,101                     | 05/03/02                    |                                     | MALVOLTI et al            |
| 208858US0 PCT        | 09/831,888                     | 07/19/01                    |                                     | LEWIS et al               |
| 04158-0014-0 PCT     | 09/147,669                     | 02/24/99                    |                                     | LEWIS et al               |

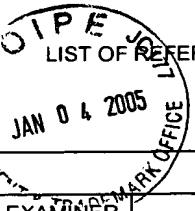
\*Present Application; listed for information

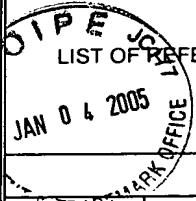
| Form PTO 1449<br>(Modified)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |          | ATTY DOCKET NO.<br>217941US0PCT | SERIAL NO.<br>10/030,101   |           |                            |
|--|----|---|----------|---------------------------------|--|-----------|----------------------------|
| P E<br>LIST OF REFERENCES CITED BY APPLICANT<br>JUN 04 2005  |    | APPLICANT<br>Chiara MALVOTI, et al.   |          |                                 |  |           |                            |
|  |    | FILING DATE<br>May 3, 2002  |          | GROUP<br>1616                   |  |           |                            |
| <b>U.S. PATENT DOCUMENTS</b>   |    |   |          |                                 |  |           |                            |
| EXAMINER INITIAL   |    | DOCUMENT NUMBER   | DATE     | NAME                            | CLASS  | SUB CLASS | FILING DATE IF APPROPRIATE |
|  | AA | 6,290,930   | 09/18/01 | Frank E. BLONDINO et al         |  |           |                            |
|  | AB | 2003/0190287 A1   | 10/09/03 | David LEWIS et al               |  |           |                            |
|  | AC | 2003/0206870 A1   | 11/06/03 | David LEWIS et al               |  |           |                            |
|  | AD | 5,653,961   | 08/05/97 | Rebecca A. McNALLY et al        |  |           |                            |
|  | AE | 6,451,285   | 09/17/02 | Frank E. BLONDINO et al         |  |           |                            |
|  | AF | 2003/0077230 A1   | 04/24/03 | Frank E. BLONDINO et al         |  |           |                            |
|  | AG | 6,645,466   | 11/11/03 | Manfred KELLER et al            |  |           |                            |
|  | AH | 6,149,892   | 11/21/00 | Ignatius Loy BRITTO             |  |           |                            |
|  | AI | 5,695,743   | 12/09/97 | Tarlochan S. PUREWAL et al      |  |           |                            |
|  | AJ | 5,683,677   | 11/04/97 | Tarlochan S. PUREWAL et al      |  |           |                            |
|  | AK | 6,026,808   | 02/22/00 | Thomas Alex ARMER et al         |  |           |                            |
|  | AL | 6,045,778   | 04/04/00 | Paul Donald JAGER et al         |  |           |                            |
|  | AM | 2001/0031244 A1   | 10/18/01 | David LEWIS et al               |  |           |                            |
|  | AN | 6,006,745   | 12/28/99 | Paul E. MARECKI et al           |  |           |                            |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |   |          |                                 |  |           |                            |
|  |    | DOCUMENT NUMBER   | DATE     | COUNTRY                         | TRANSLATION<br>YES   | NO        |                            |
|  | AO | WO 98/56349   | 12/17/98 | WIPO                            |  |           |                            |
|  | AP | WO 98/34595   | 08/13/98 | WIPO (w/English Abstract)       |  | XXX       |                            |
|  | AQ | WO 92/11236   | 07/09/92 | WIPO                            |  |           |                            |
|  | AR | WO 96/32150   | 10/17/96 | WIPO                            |  |           |                            |
|  | AS | WO 96/32151   | 10/17/96 | WIPO                            |  |           |                            |
|  | AT | WO 96/32345   | 10/17/96 | WIPO                            |  |           |                            |
|  | AU | WO 95/17195   | 06/29/95 | WIPO                            |  |           |                            |
|  | AV | 0 504 112 A2  | 09/16/92 | EPO (w/English Abstract)        |  | XXX       |                            |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |    |   |          |                                 |  |           |                            |
|  | AW | R.O. Williams III et al, "A study of an epoxy aerosol can lining exposed to hydrofluoroalkane propellants", <u>EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS</u> , Vol. 44, pp. 195-203, (1997). |          |                                 |  |           |                            |
|  | AX | <u>ABPI COMPENDIUM OF DATA SHEETS AND SUMMARIES OF PRODUCT CHARACTERISTICS</u> , Datapharm Publications Limited, London, pp. 81-82, (1996-97).  |          |                                 |  |           |                            |
|  | AY | Paul A. Sanders, Ph.D., "Homogeneous Systems and Their Properties", <u>HANDBOOK OF AEROSOL TECHNOLOGY</u> , Second Edition, Van Nostrand Reinhold Company, NY, pg. 30, 1979.                              |          |                                 |  |           |                            |
|  | AZ | G. Brambilla et al, "Modulation of Aerosol Clouds Produced by HFA Solution Inhalers", <u>PORTABLE INHALERS</u> , pp. 155-159, (November 26 & 27, 1998).   |          |                                 | <input type="checkbox"/> Additional References sheet(s) attached |           |                            |
| Examiner   |    |   |          |                                 | Date Considered  |           |                            |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |   |          |                                 |  |           |                            |

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| U.S. PATENT DOCUMENTS  |             |   |          |                                 |  |              |                               |
| EXAMINER<br>INITIAL  | MARK OFFICE | DOCUMENT<br>NUMBER  | DATE     | NAME                            | CLASS  | SUB<br>CLASS | FILING DATE<br>IF APPROPRIATE |
|  | BA          | 5,954,047   | 09/21/99 | Thomas Alex ARMER et al         |  |              |                               |
|  | BB          | 5,435,297   | 07/25/95 | Christoph KLEIN                 |  |              |                               |
|  | BC          | 3,361,306   | 01/02/68 | W. M. GRIM                      |  |              |                               |
|  | BD          | 3,622,053   | 11/23/71 | John V. RYDEN                   |  |              |                               |
|  | BE          | 2003/0157028 A1   | 08/21/03 | David LEWIS et al               |  |              |                               |
|  | BF          | 2003/0190289 A1   | 10/09/03 | David LEWIS et al               |  |              |                               |
|  | BG          | 4,835,145   | 05/30/89 | Peter MacDONALD                 |  |              |                               |
|  | BH          | 5,676,930   | 10/14/97 | Paul D. JAGER                   |  |              |                               |
|  | BI          | 6,413,496   | 07/02/02 | Michael GOODMAN et al           |  |              |                               |
|  | BJ          | 5,642,728   | 07/01/97 | Jan ANDERSSON et al             |  |              |                               |
|  | BK          | 5,415,853   | 05/16/95 | Helmut HETTCHE et al            |  |              |                               |
|  | BL          | 5,605,674   | 02/25/97 | Tarlochan S. PUREWAL et al      |  |              |                               |
|  | BM          | 6,315,985   | 11/13/01 | Zheng Z. WU et al               |  |              |                               |
|  | BN          | 6,131,566   | 10/17/00 | Ian Carl ASHURST                |  |              |                               |
| FOREIGN PATENT DOCUMENTS   |             |   |          |                                 |  |              |                               |
|  |             | DOCUMENT<br>NUMBER  | DATE     | COUNTRY                         | TRANSLATION<br>YES   | NO           |                               |
|  | BO          | WO 93/05765   | 04/01/93 | WIPO                            |  |              |                               |
|  | BP          | WO 93/18746   | 09/30/93 | WIPO (w/English Abstract)       |  | XXX          |                               |
|  | BQ          | WO 94/21229   | 09/29/94 | WIPO                            |  |              |                               |
|  | BR          | WO 93/11743   | 06/24/93 | WIPO                            |  |              |                               |
|  | BS          | WO 98/01147   | 01/15/98 | WIPO                            |  |              |                               |
|  | BT          | WO 98/13031   | 04/02/98 | WIPO                            |  |              |                               |
|  | BU          | WO 00/35458   | 06/22/00 | WIPO                            |  |              |                               |
|  | BV          | WO 00/78286   | 12/28/00 | WIPO                            |  |              |                               |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)  |             |   |          |                                 |  |              |                               |
|  | BW          | B. Meakin, "Fine Particle Dose Control of Solution Based pMDIs", <u>DRUG DELIVERY TO THE LUNGS IX</u> , The Aerosol Society, pp. 1-20, (December 14 & 15, 1998).  |          |                                 |  |              |                               |
|  | BX          | Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", <u>Respiratory Drug Delivery V</u> , 1996, pp. 133-144. |          |                                 |  |              |                               |
|  | BY          | L. Harrison et al, "Twenty-eight-day Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in Healthy Subjects", <u>J. Pharm. Pharmacol.</u> , 1996, Vol. 48, pp. 596-600.                           |          |                                 |  |              |                               |
|  | BZ          | P. Hoet et al, "Epidemic of liver disease caused by hydrochlorofluorocarbons used as ozone-sparing substitutes of chlorofluorocarbons", <u>The Lancet</u> , 1997, Vol. 350, pp. 556-559.                          |          |                                 | <input type="checkbox"/> Additional References sheet(s) attached |              |                               |
| Examiner   |             |   |          |                                 | Date Considered  |              |                               |
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| U.S. PATENT DOCUMENTS  |   |  |                                 |                                 |  |                            |
| EXAMINER INITIAL   | DOCUMENT NUMBER   | DATE   | NAME                            | CLASS                           | SUB CLASS  | FILING DATE IF APPROPRIATE |
| CA   | 2004/0047809 A1   | 03/11/04   | David LEWIS et al               |                                 |  |                            |
| CB   | 5,891,419   | 04/06/99   | Anthony J. CUTIE                |                                 |  |                            |
| CC   | 5,192,528   | 03/09/93   | R. RADHAKRISHNAN et al          |                                 |  |                            |
| CD   | 4,185,100   | 01/22/80   | David T. ROVEE et al            |                                 |  |                            |
| CE   | 6,253,762   | 07/03/01   | Ignatius Loy BRITTO             |                                 |  |                            |
| CF   | 6,713,047   | 03/30/04   | David LEWIS et al               |                                 |  |                            |
| CG   | 2003/0066525  | 04/10/03   | David LEWIS et al               |                                 |  |                            |
| CH   | 6,716,414   | 04/06/04   | David LEWIS et al               |                                 |  |                            |
| CI   | 2004/0062720  | 04/01/04   | David LEWIS et al               |                                 |  |                            |
| CJ   | 2004/0096399  | 05/20/04   | David LEWIS et al               |                                 |  |                            |
| CK   | 4,499,108   | 02/12/85   | Joel A. SEQUEIRA et al          |                                 |  |                            |
| CL   | 5,955,058   | 09/21/99   | Paul Donald JAGER et al         |                                 |  |                            |
| CM   | 6,150,418   | 11/21/00   | Dieter HOCHRAINER et al         |                                 |  |                            |
| CN   | 6,143,277   | 11/07/00   | Ian ASHURST et al               |                                 |  |                            |
| FOREIGN PATENT DOCUMENTS   |   |  |                                 |                                 |  |                            |
|  | DOCUMENT NUMBER   | DATE   | COUNTRY                         | TRANSLATION                     |  |                            |
|  |   |  |                                 | YES                             | NO   |                            |
| CO   | WO 99/65460   | 12/23/99   | WIPO                            |                                 |  |                            |
| CP   | 0 642 992 A2  | 03/15/95   | EPO (English Abstract provided) |                                 |  | XXX                        |
| CQ   | WO 98/24420   | 06/11/98   | WIPO                            |                                 |  |                            |
| CR   | 0 372 777   | 06/13/90   | EPO                             |                                 |  |                            |
| CS   | 0 911 048   | 04/28/99   | EPO                             |                                 |  |                            |
| CT   | WO 99/12596   | 03/18/99   | WIPO                            |                                 |  |                            |
| CU   | WO 92/20391   | 11/26/92   | WIPO                            |                                 |  |                            |
| CV   | WO 98/03533   | 01/29/98   | WIPO                            |                                 |  |                            |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)  |   |  |                                 |                                 |  |                            |
| CW   | J. Daly, Jr., "Properties and toxicology of CFC alternatives", <u>Aerosol Age</u> , February 1990, pp. 26-27, 40, 56 and 57.  |  |                                 |                                 |  |                            |
| CX   | D. Strobach, "Alternatives to CFCs" Part II, <u>Aerosol Age</u> , July 1988, pp. 32-33, 42 and 43   |  |                                 |                                 |  |                            |
| CY   | Tsi-Zong Tzou et al, "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", <u>Journal of Pharmaceutical Sciences</u> , 1997, Vol. 86, No. 12, pp. 1352-1357. |  |                                 |                                 |  |                            |
| CZ   | M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", <u>Journal of Aerosol Medicine</u> , 1991, Vol. 4, No. 3, pp. 181-187.  |  |                                 |                                 | <input type="checkbox"/> Additional References sheet(s) attached |                            |
| Examiner   |   |  |                                 | Date Considered                 |  |                            |
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| O P E R A T I O N S<br>JAN 01 2005<br>U. S. PATENT AND TRADEMARK OFFICE<br>LIST OF REFERENCES CITED BY APPLICANT   |    | APPLICANT<br>Chiara MALVOTI, et al.  |          |                                 |  |              |                               |
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| EXAMINER<br>INITIAL  |    | DOCUMENT<br>NUMBER   | DATE     | NAME                            | CLASS  | SUB<br>CLASS | FILING DATE<br>IF APPROPRIATE |
|  | DA | 6,045,784  | 04/04/00 | Nicholas Arthur RUEBUSCH et al  |  |              |                               |
|  | DB | 2003/0089369   | 05/15/03 | David LEWIS et al               |  |              |                               |
|  | DC | 2004/0184993   | 09/23/04 | David LEWIS et al               |  |              |                               |
|  | DD |  |          |                                 |  |              |                               |
|  | DE |  |          |                                 |  |              |                               |
|  | DF |  |          |                                 |  |              |                               |
|  | DG |  |          |                                 |  |              |                               |
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|  | DN |  |          |                                 |  |              |                               |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |  |          |                                 |  |              |                               |
|  |    | DOCUMENT<br>NUMBER   | DATE     | COUNTRY                         | TRANSLATION<br>YES   | NO           |                               |
|  | DO | WO 96/32099  | 10/17/96 | WIPO                            |  |              |                               |
|  | DP | WO 00/23065  | 04/27/00 | WIPO (w/English Abstract)       |  | XXX          |                               |
|  | DQ | WO 94/14490  | 07/07/94 | WIPO (w/English Abstract)       |  | XXX          |                               |
|  | DR | WO 99/64014  | 12/16/99 | WIPO                            |  |              |                               |
|  | DS | WO 00/30608  | 06/02/00 | WIPO                            |  |              |                               |
|  | DT | WO 00/53157  | 09/14/00 | WIPO                            |  |              |                               |
|  | DU | WO 97/47286  | 12/18/97 | WIPO                            |  |              |                               |
|  | DV | 2 326 334  | 12/23/98 | GB                              |  |              |                               |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |    |  |          |                                 |  |              |                               |
|  | DW | I. P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", <u>The Pharmaceutical Journal</u> , 1997, Vol. 259, pp. 896-898.   |          |                                 |  |              |                               |
|  | DX | D. Tiwari et al, "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, <u>Drug Development and Industrial Pharmacy</u> , 1998, Vol. 24, No. 4, pp. 345-352.                               |          |                                 |  |              |                               |
|  | DY | <u>Handbook of Pharmaceutical Excipients</u> , 3rd Ed., Kibbe Editor, pp. 7-9, 220-222, 234-235 and 560-561.   |          |                                 |  |              |                               |
|  | DZ | L. I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", <u>Biopharmaceutics &amp; Drug Disposition</u> , 1997, Vol. 18, No. 7, pp. 635-643. |          |                                 | <input type="checkbox"/> Additional References sheet(s) attached |              |                               |
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|   | EA |  |          |                                     |             |                          |  |
|   | EB |  |          |                                     |             |                          |  |
|   | EC |  |          |                                     |             |                          |  |
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|   | EG |  |          |                                     |             |                          |  |
|   | EH |  |          |                                     |             |                          |  |
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|   | EK |  |          |                                     |             |                          |  |
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|   | EM |  |          |                                     |             |                          |  |
|   | EN |  |          |                                     |             |                          |  |
| <b>FOREIGN PATENT DOCUMENTS</b>   |    |  |          |                                     |             |                          |  |
|   |    | DOCUMENT<br>NUMBER   | DATE     | COUNTRY                             | TRANSLATION |                          |  |
|   | EO | 0 653 204  | 05/17/95 | EPO                                 | YES         |                          | NO   |
|   | EP | WO 01/47493  | 07/05/01 | WIPO                                |             |                          |  |
|   | EQ | WO 91/11173  | 08/08/91 | WIPO                                |             |                          |  |
|   | ER | WO 93/11747  | 06/24/93 | WIPO                                |             |                          |  |
|   | ES | WO 94/21228  | 09/29/94 | WIPO                                |             |                          |  |
|   | ET | WO 96/18384  | 06/20/96 | WIPO                                |             |                          |  |
|   | EU | WO 96/19198  | 06/27/96 | WIPO                                |             |                          |  |
|   | EV | WO 96/19968  | 07/04/96 | WIPO                                |             |                          |  |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>  |    |  |          |                                     |             |                          |  |
|   | EW |  |          |                                     |             |                          |  |
|   | EX |  |          |                                     |             |                          |  |
|   | EY |  |          |                                     |             |                          |  |
|   | EZ |  |          |                                     |             |                          | <input type="checkbox"/> Additional References sheet(s) attached |
| Examiner  |    |  |          |                                     |             | Date Considered          |  |
| <small>*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> |    |  |          |                                     |             |                          |  |

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|--|----|--|----------|---------------------------------|-----------------|--|----------------------------|
| <br>LIST OF REFERENCES CITED BY APPLICANT  |    | APPLICANT  |          | Chiara MALVOTI, et al.          |                 |  |                            |
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|  |    | May 3, 2002  |          | 1616                            |                 |  |                            |
| <b>U.S. PATENT DOCUMENTS</b>   |    |  |          |                                 |                 |  |                            |
| EXAMINER INITIAL   |    | DOCUMENT NUMBER  | DATE     | NAME                            | CLASS           | SUB CLASS  | FILING DATE IF APPROPRIATE |
| FA   |    |  |          |                                 |                 |  |                            |
| FB   |    |  |          |                                 |                 |  |                            |
| FC   |    |  |          |                                 |                 |  |                            |
| FD   |    |  |          |                                 |                 |  |                            |
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| FF   |    |  |          |                                 |                 |  |                            |
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| FI   |    |  |          |                                 |                 |  |                            |
| FJ   |    |  |          |                                 |                 |  |                            |
| FK   |    |  |          |                                 |                 |  |                            |
| FL   |    |  |          |                                 |                 |  |                            |
| FM   |    |  |          |                                 |                 |  |                            |
| FN   |    |  |          |                                 |                 |  |                            |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |  |          |                                 |                 |  |                            |
|  |    | DOCUMENT NUMBER  | DATE     | COUNTRY                         | TRANSLATION     |  |                            |
|  | FO | WO 98/05302  | 02/12/98 | WIPO                            | YES             | NO   |                            |
|  | FP | WO 00/07567  | 02/17/00 | WIPO (w/English Abstract)       |                 |  | XXX                        |
|  | FQ | WO 98/34596  | 08/13/98 | WIPO                            |                 |  |                            |
|  | FR | WO 94/13262  | 06/23/94 | WIPO                            |                 |  |                            |
|  | FS | WO 00/06121  | 02/10/00 | WIPO (w/English Abstract)       |                 |  | XXX                        |
|  | FT | WO 99/65464  | 12/23/99 | WIPO                            |                 |  |                            |
|  | FU |  |          |                                 |                 |  |                            |
|  | FV |  |          |                                 |                 |  |                            |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |    |  |          |                                 |                 |  |                            |
|  | FW |  |          |                                 |                 |  |                            |
|  | FX |  |          |                                 |                 |  |                            |
|  | FY |  |          |                                 |                 |  |                            |
|  | FZ |  |          |                                 |                 | <input type="checkbox"/> Additional References sheet(s) attached |                            |
| Examiner   |    |  |          |                                 | Date Considered |  |                            |
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